

Docket No. 242993US55CONT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: Bernhard O. PALSSON, et al.

SERIAL NO: New U.S. Application

FILED: Herewith

FOR: METHODS FOR REGULATING THE SPECIFIC LINEAGES OF CELLS PRODUCED IN A HUMAN HEMATOPOIETIC CELL CULTURE, METHODS FOR ASSAYING THE EFFECT OF SUBSTANCES ON LINEAGE-SPECIFIC CELL PRODUCTION, AND CELL COMPOSITIONS PRODUCED BY THESE CULTURES

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR 1.97

COMMISSIONER FOR PATENTS
ALEXANDRIA, VIRGINIA 22313

SIR:

Applicant(s) wish to disclose the following information.

REFERENCES

- ☒ The applicant(s) wish to make of record the references listed on the attached form PTO-1449. Copies of the listed references are attached, where required, as are either statements of relevancy or any readily available English translations of pertinent portions of any non-English language references.
- ☐ A check or credit card payment form is attached in the amount required under 37 CFR §1.17(p).

RELATED CASES

- ☐ Attached is a list of applicant's pending application(s) or issued patent(s) which may be related to the present application. A copy of the patent(s), together with a copy of the claims and drawings of the pending application(s) is attached along with PTO 1449.
- ☐ A check or credit card payment form is attached in the amount required under 37 CFR §1.17(p).

CERTIFICATION

- ☐ Each item of information contained in this information disclosure statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement.
- ☐ No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned, having made reasonable inquiry, was known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this statement.

DEPOSIT ACCOUNT

- ☒ Please charge any additional fees for the papers being filed herewith and for which no check or credit card payment is enclosed herewith, or credit any overpayment to deposit account number 15-0030. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.



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Form PTO 1449
(Modified)U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICEATTY DOCKET NO.
242993US55CONTSERIAL NO.
NEW U.S. APPLICATION

LIST OF REFERENCES CITED BY APPLICANT

APPLICANT

Bernhard O. PALSSON, et al .

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Herewith

GROUP

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	AA	6,326,198	12/04/01	Emerson et al			
	AB	6,299,650	10/09/01	Van Blitterswijk et al			
	AC	5,811,094	09/22/98	Caplan et al			
	AO	5,646,043	07/08/97	Emerson et al			
	AE	4,135,975	01/23/79	Lichtman et al			
	AF	4,514,499	04/30/85	Noll			
	AG	4,861,714	08/29/89	Dean et al			
	AH	5,032,407	07/16/91	Wagner et al			
	AI	5,605,822	02/25/97	Emerson et al			
	AJ	5,670,351	09/23/97	Emerson et al			
	AK	4,481,946	11/13/84	Altshuler et al			
	AL	4,714,680	12/22/87	Civin			
	AM	4,889,812	12/26/89	Guinn et al			
	AN	5,032,508	07/16/91	Naughton et al			

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION	
					YES	NO
	AO	90/15877A2	12/27/90	WIPO w/Abstract		
	AP	95/06409	03/09/95	WIPO w/Abstract		
	AQ	0 358 506	03/14/90	Europe w/Abstract		
	AR	0 455 482	11/06/91	Europe w/Abstract		
	AS	93/18136	09/16/93	WIPO w/Abstract		
	AT	93/18137	09/16/93	WIPO w/Abstract		
	AU					
	AV					

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	AW	M. W. Glacken et al., "Mammalian cell culture: engineering principles and scale-up", Trends in Biotechnology, Vol. 1, No. 4, 1983, PP. 102-108
	AX	Steven A. ROSENBERG et al., "In Vitro Growth of Murine T Cells II. Growth of in Vitro Sensitized Cells Cytotoxic for Alloantigens", The Journal of Immunology, Vol. 121, No. 5. November 1978, PP. 1951-1955
	AY	W. French ANDERSON, "Prospects for Human Gene Therapy", Science, Vol. 26, October 26, 1987, pp. 401-409
	AZ	T.M. Dexter, "The Message in the medium", Nature, Vol. 309, June 1984, pp 746-747

Examiner

Date Considered

*Examiner: Initial if reference is considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	BA	5,945,225	08/31/99	Speith-Herfurth et al			
	BB	5,670,147	09/23/97	Emerson et al			
	BC	5,199,942	04/06/93	Gillis			
	BD	4,808,611	02/28/89	Cosman			
	BE	4,963,489	10/16/90	Naughton et al			
	BF	5,061,620	10/29/91	Tsakamoto et al			
	BG	5,922,597	07/13/99	Verfaillie et al			
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	BI	4,810,643	03/07/89	Souza			
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	BK	5,851,832	12/22/98	Weiss et al			
	BL	5,635,386	06/03/97	Palsson et al			
	BM	4,486,188	12/04/84	Altshuler et al			
	BN	4,847,201	07/11/89	Kaswasaki et al			
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION YES NO		
	BO						
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OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)							
	BW	Manfred R. Koller, et al. "Expansion of Primitive Human Hematopoietic Progenitors in a Perfusion Bioreactor System with LL-3, LL-6, and Stem Cell Factor", Biotechnology, Vol. 11, March, 1993, pp. 358-363					
	BX	Bernhard O. PALSSON et al, "Expansion of Human Bone Marrow Progenitor Cells in a High Cell Density Continuous Perfusion System", Biotechnology, Vol. 11, March, 1993, pp. 368-372					
	BY	Giovanni MIGLIACCIO et al., "In Vitro Differentiation of Human Granulocyte/Macrophage and Erythroid Progenitors: Comparative Analysis of the Influence of Recombinant Human Erythropoietin, G-CSF, GM-CSF, and IL-3 in Serum-Supplemented and Serum-Deprived Cultures", Blood, Vol. 72, No. 1 July 1988, pp. 248-255					
	BZ	Ian K. McNiece et al., "Studies on the Myeloid Synergistic Factor From 5637: Comparison with Interleukin-1 Alpha", Blood, Vol. 73, No. 4 (March), 1989, pp. 919-923					
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	CB	5,851,832	12/22/98	Weiss et al			
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	CW	Paul BAINES et al., Exp. Hematol. 16:785-789 (1988)
	CX	Jan A. NOLTA et al., Human Gene Therapy, 1:257-268 (1990)
	CY	John R. STEPHENSON et al., Proc. Nat. Acad. Sci. U.S.A., Vol. 68, No. 7, pp. 1542-1546, July 1971
	CZ	Giovanni MIGLIACCIO et al., Exp. Hematol. 18:1049-1055 (1990)

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	DW	Richard M. Schwartz et al., "In Vitro Myelopoiesis Stimulated by Rapid Medium Exchange and Supplementation With Hematopoietic Growth Factors", Blood, Vol 78, No. 12, December 15, 1991, pp. 3155-3161
	DX	Rob E. Ploemacher et al., "Use of Limiting-Dilution Type Long-Term Marrow Cultures in Frequency Analysis of Marrow-Repopulating and Spleen Colony-Forming Hematopoietic Stem Cells in the Mouse", Blood, Vol 78, No. 10 (November 15, 1991, pp. 2527-2533
	DY	Manfred R. Koller et al., "Effects of Synergistic Cytokine Combinations, Low Oxygen, and Irradiated Stroma on the Expansion of Human Cord Blood Progenitors", Blood, Vol 80, No. 2 (July 15, 1992), pp. 403-411
	DZ	J. AIKEN et al., Journal of Pediatric Surgery, Vol. 25, No. 1 (January), 1990; pp. 140-145

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OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)							
	EW	C. FAVRE et al., "Interleukin-4 has Basophilic and Eosinophilic Cell Growth-Promoting Activity on Cord Blood Cells", Blood, Vol. 1, January 1, 1990, pp. 67-73					
	EX	Yoichi TAKAUE et al., "Limiting-Dilution Analysis of the Effects of Colony-Stimulating Factors, Phytohemagglutinin, and Hydrocortisone on Hematopoietic Progenitor Cell Growth", Blood, Vol. 70, No. 5, November, 1987, pp. 1611-1618					
	EY	Yoichi TAKAUE et al., "Effect of Recombinant Human G-CSF, GM-CSF, IL-3, and IL-1 α on the Growth of Purified Human Peripheral Blood Progenitors", Blood, Vol. 76, No. 2, July 15, 1990, pp. 330-335					
	EZ	H. J. Sutherland et al., "Alternative Mechanisms With and Without Steel Factor Support Primitive Human Hematopoiesis", Blood, Vol. 81, No. 6, March 15, 1993, pp. 1465-1470					
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	FW	Lucia H. Coutinho et al., "Effects of Recombinant Human Granulocyte Colony-Stimulating Factor (CSF), Human Granulocyte Macrophage-CSF, and Gibbon Interleukin-3 on Hematopoiesis in Human Long-Term Bone Marrow Culture", Blood, Vol. 11, June 1, 1990, pp. 2118-2129
	FX	Susan C. GUBA et al., "Bone Marrow Stromal Fibroblasts Secrete Interleukin-6 and Granulocyte-Macrophage Colony-Stimulating Factor in the Absence of Inflammatory Stimulation: Demonstration by Serum-Free Bioassay, Enzyme-Linked Immunosorbent Assay, and Reverse Transcriptase Polymerase Chain Reaction", Blood, Vol. 80, No. 5, September 1, 1992, pp. 1190-1198
	FY	Richard M. SCHWARTZ et al., "Rapid medium perfusion rate significantly increases the productivity and longevity of human bone marrow cultures", Proc. Natl. Acad. Sci. USA, Vol. 88, pp. 6760-6764, August 1991
	FZ	David E. HARRISON et al., "Primitive hemopoietic stem cells: direct assay of most productive populations by competitive repopulation with simple binomial, correlation and covariance calculations", Experimental Hematology 21:206-219 (1993)

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OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)

	GW	D. KRUMWIEH et al., "Preclinical Studies on Synergistic Effects of IL-1, IL-3, G-CSF and GM-CSF in Cynomolgus Monkeys", International Journal of Cell Cloning 8:229-248, Suppl. 1 (1990)
	GX	Makio OGAWA, Ph.D., "Effects of Hemopoietic Growth Factors on Stem Cells in Vitro", Hematology/Oncology Clinics of North America, Vol. 3(3) September 1989, pp. 453-464
	GY	Jerry CALDWELL et al., "Culture Perfusion Schedules Influence the Metabolic Activity and Granulocyte-Macrophage Colony-Stimulating Factor Production Rates of Human Bone Marrow Stromal Cells", Journal of Cellular Physiology, 147:344-353 (1991)
	GZ	C.M. HEYWORTH et al., "The Role of Hemopoietic Growth Factors in Self-Renewal and Differentiation of IL-3-Dependent Multipotential Stem Cells", Growth Factors, 1990, Vol. 2, pp. 197-211

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OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)							
	HW	Shiang HUANG et al., "Formation of haematopoietic Microenvironment and haematopoietic stem cells from single human bone marrow stem cells", Nature, Vol. 360, 24/31 December 1992, pp. 745-749					
	HX	Randy A. HOCK et al., "Retrovirus-mediated transfer and expression of drug resistance genes in human haematopoietic progenitor cells", Nature, Vol. 320, March 1986, pp. 275-277					
	HY	A.A. FAUSER et al., "Granuloerythropoietic Colonies in Human Bone Marrow, Peripheral Blood, and Cord Blood" Blood, Vol. 52, No. 6, December 1978, pp. 1243-1248					
	HZ	C.D. MYERS et al., "A Cell Line Secreting Stimulating Factors for CFU-GEMM Culture", Blood, Vol. 64, No. 1 (July) 1984, pp. 152-155					
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OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)							
	IW	Alice M. WANG et al., "Molecular Cloning of the Complementary DNA for Human Tumor Necrosis Factor", Science, Vol. 228, 20 November 1984, pp. 149-154					
	IX	Colin A. SIEFF et al., "Human Recombinant Granulocyte-Macrophage Colony-Stimulating Factor: A Multilineage Hematopoietin" Science, Vol. 230, 6 December 1985, pp. 1171-1173					
	IY	Robert E. DONAHUTE et al., "Human IL-3 and GM-CSF Act Synergistically in Stimulating Hematopoiesis in Primates", Science, Vol. 241, 30 September 1988, pp. 1820-1823					
	IZ	Ronald H. SCHWARTZ, "A Cell Culture Model for T Lymphocyte Clonal Anergy", Science, Vol. 248, 15 June 1990, pp. 1349-1356					
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OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)							
	JW	Toshio SUDA et al., "A Stimulatory Effect of Recombinant Murine Interleukin-7 (IL-7) on B-Cell Colony Formation and an Inhibitory Effect of IL-1 α ", Blood, Vol. 74, No. 6, November 1, 1989, pp. 1936-1941					
	JX	Heather J. SUTHERLAND et al., "Characterization and Partial Purification of Human Marrow Cells Capable of Initiating Long-Term Hematopoiesis In Vitro", Blood, Vol. 74, No. 5 (October), 1989; pp. 1563-1570					
	JY	Sem SEELAND et al., "Combined and Sequential Effects of Human IL-3 and GM-CSF on the Proliferation of CD34+ Hematopoietic Cells From Cord Blood", Blood, Vol. 73, No. 5, (April), 1989; pp. 1195-1201					
	JZ	Sallie S. BOGGS, "Targeted Gene Modification for Gene Therapy of Stem Cells", International Journal of Cell Cloning 8:80-96 (1990)					
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OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)							
	KW	Cynthia E. DUNBAR et al., "Gene Transfer into Hematopoietic Progenitor and Stem Cells: Progress and Problems", Stem Cells 1994;12:563-576					
	KX	Angelika MUELLER, "Die Knochenmarkstammzellkultur Technische Voraussetzungen und klinische Einsatzmoeglichkeiten", Folia Haematol., Leipzig 116 (1989) 5, 731-743					
	KY	Stephen G. EMERSON et al., "Purification of Fetal Hematopoietic Progenitors and Demonstration of Recombinant Multipotential Colony-stimulating Activity", The Journal of Clinical Investigation, Vol. 76, September 1985, 1286-1290					
	KZ	pp. 573-578: "Clinical Transplantation", In <u>Immunology</u> , Second Edition, J. Kuby, W.H. Freeman and Company, New York (1994)					
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OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)							
	LW	Theodore FRIEDMANN, "Overcoming the Obstacles-Treating disease by providing needed genes remains a compelling idea, but clinical and basic researchers still have much to do before gene therapy can live up to its promise", Scientific American, June 1997, pp. 96-101					
	LX	Joseph FEDER et al., "The Large-Scale Cultivation of Mammalian Cells", Scientific American, Vol. 248, No. 1 (January 1983), pp. 24-31					
	LY	Heather J. SUTHERLAND, "Functional characterization of individual human hematopoietic stem cells cultured at limiting dilution on supportive marrow stromal layers", Proc. Natl. Acad. Sci. USA, Vol. 87 (1990), pp. 3584-3588					
	LZ	Janice L. GABRILOVE et al., "Pluripoietin α : A second human hematopoietic colony-stimulating factor produced by the human bladder carcinoma cell line 5637", Proc. Natl. Acad. Sci. USA, Vol. 83, pp. 2478-2482, April 1986					
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OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)								
	MW	Jeffrey A. HUBBELL et al., "Endothelial Cell-Selective Materials for Tissue Engineering in the Vascular Graft Via a New Receptor, Biotechnology, Vol. 9, June 1991, pp. 568-572						
	MX	Jerry CALDWELL et al., "Influence of Medium Exchange Schedules on Metabolic, Growth, and GM-CSF Secretion Rates of Genetically Engineered NIH-3T3 Cells", Biotechnology Progress, Vol. 7, No. 1, January/February 1991, pp. 1-8						
	MY	Li Lu et al., "Effect of recombinant and purified human haematopoietic growth factors on in vitro colony formation by enriched populations of human megakaryocyte progenitor cells", British Journal of Haematology, 1988, Vol. 70, pp. 149-156						
	MZ	A. Montes BORINAGA et al., "Interleukin-6 is a cofactor for the growth of myeloid cells from human bone marrow aspirates but does not affect the clonogenicity of myeloma cells in vitro", British Journal of Haematology, 1990, No. 76, pp. 476-483						
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	NW	P.M. LEHN., "Gene therapy using bone marrow transplantation: a 1990 update", Bone Marrow Transplantation (1990), No. 5. pp. 287-293					
	NX	Manfred R. KOLLER et al., "Beneficial Effects of Reduced Oxygen Tension and Perfusion in Long-Term Hematopoietic Cultures", Biochemical Engineering, VII, Vol. 665 of the Annals New York Academy of Sciences, pp. 105-116, (October 1992)					
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	NZ	John BRANDT et al., "Detection of Human Hematopoietic Progenitor Cell Capable of Forming Blast Cell Containing Colonies <u>In Vitro</u> ", Advances in Experimental Medicine and Biology, Vol. 241, pp. 165-173					
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	OW	C.J. EAVES et al., "The Human Hematopoietic Stem Cell In Vitro and In Vivo", Blood Cells (1992) 18:301-307						
	OX	Masaaki ISHIZUKA et al., "Mitogenic Effect of Bestatin on Lymphocytes", The Journal of Antibiotics, Vol. 33, No. 6, (June 1980), pp. 653-662						
	OY	Donald B. Kohn Ph.D. et al., "Gene Therapy for Genetic Diseases", Cancer Investigation, 7(2), pp. 179-192 (1989)						
	OZ	Maria PODOLAK-DAWIDZIAK et al., "Does Human Bladder Carcinoma Cell Line 5637-Conditioned Medium Supplement the Growth of Megakaryocyte Colonies (CFU-Mk) in Cultures of Human bone Marrow", Haematologia, 23:121-123						
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PW	Jan A. NOLTA et al., "Comparison of the Effects of Growth Factors on Retroviral Vecto-Mediated Gene Transfer and the Proliferative Status of Human Hematopoietic Progenitor Cells", Human Gene Therapy, 1:257-268 (1990)
PY	Christoph HEBERLEIN et al., "The Gene for Erythropoietin Receptor is Expressed in Multipotential Hematopoietic and Embryonal Stem Cells: Evidence for Differentiation Stage-Specific Regulation", Molecular and Cellular Biology, Vol. 12 (14) pp. 1815-1826, (1992)
PY	Nicholas DAINLAK et al., "Interactions of Insulin, Insulinlike Growth Factor II, and Platelet-derived Growth Factor in Erythropoietic Culture", J. Clin. Invest. Vol. 76, September 1985, 1237-1242
PZ	Yves-Jacques SCHNEIDER et al., "Monoclonal Antibody Production in Semi-Continuous Serum-and protein-free culture", Journal of Immunological Methods, Vol. 129 (1990) pp.251-268

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	QW	Philip W. KANTOFF et al., "Expression of Human Adenosine Deaminase in Nonhuman Primates after Retrovirus-Mediated Gene Transfer", J. Exp. Med. Volume 166, July 1987, pp. 219-234.					
	QX	Suzanne GARTNER et al., "Long-term culture of human bone marrow cells", Proc. Natl. Acad. Sci. USA, Vol. 77, No. 8, pp. 4756-4759, August 1980					
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	RW	E. Morioka et al, "Purification of a granulocyte colony-stimulating factor from the conditioned medium of a subclone of human bladder carcinoma cell line 5637, HTB9", Res. Exp. Med. (1990), 190:229-238					
	RX	Steven A. ROSENBERG et al., "In Vitro Growth of Murine T Cells II. Growth of in Vitro Sensitized Cells Cytotoxic for Alloantigens", The Journal of Immunology, Vol. 121, No. 5. November 1978, pp. 1951-1955					
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	RZ	S. R. ADAMSON et al., "Industrial Mammalian Cell Culture", The Canadian Journal of Chemical Engineering, Vol. 64, August 1986, pp. 531-539					
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	SX	Eastment and Rusceth, "Evaluation of Hematopoiesis in Long-Term Bone Marrow Culture: Comparison of Species Differences" In Long-Term Bone Marrow Culture, Kroc oundation Series Vol. 18, Proceeding of a Symposium Held at the Kroc Foundation Santa Ynex Valley, California, September 12-16, 1983
	SY	Clark, John Wiley & Sons, The Experimental Foundations of Modern Immunology, page 14.
	SZ	Connie J. Eaves et al., "Methodology of Long-Term Culture of Human Hemopoietic Cells", J. Tiss. Cult. Meth 13:55-62, 1991

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	TW	Yu-Chung YANG et al., "Human IL-3 (Multi-CSF): Identification by Expression Cloning of a Novel Hematopoietic Growth Factor Related to Murine IL-3", Cell, Vol. 47, pp. 3-10, October 10, 1986					
	TX	Dunbar et al., Gene transfer into hematopoietic progenitor and stem cells: Progress and problems. Stem Cells, 12:563-576					
	TY	Friedmann et al., Overcoming the obstacles to gene therapy. Sci. Am. pp. 96-101					
	TZ	Orkin and Motulsky. Report and recommendations of the panel to assess the NIH investment in research on gene therapy.					
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	UX	Kuby; Clinical Transplantation, 1994, Immunology: 573.					
	UY	R. Ian FRESHNEY, "Culture of Animal Cells A Manual of Basic Technique", (1987) Department of Medical Oncology Cancer Research Campaign Laboratories University of Glasgow, Second Addition, pp. 305-307, Alan R. Liss, Inc. (New York)					
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